

**UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

ABBVIE INC., *et al.*,

Plaintiffs,

v.

JONATHAN SKRMETTI, *in his official
capacity as* TENNESSEE ATTORNEY
GENERAL,

Defendant.

Case No. 3:25-cv-519
District Judge Aleta A. Trauger

**RESPONSE IN OPPOSITION TO
ABBVIE'S MOTION TO AMEND THE COMPLAINT**

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INTRODUCTION*

AbbVie’s request to amend its complaint should be denied as futile. Congress did not intend for the federal 340B statute to preempt the Hospital Protection Act’s claims-data provision. *See AbbVie Inc. v. Skrametti*, No. 3:25-cv-519, 2025 WL 1805271, at *10–17 (M.D. Tenn. June 30, 2025). No sub-regulatory guidance document can change this. And even if that were possible, it would not follow from the nascent circumstances alleged in AbbVie’s proposed amended complaint. AbbVie has once again failed to make the allegations needed to establish a ripe cause of action. And regardless, AbbVie’s new preemption claim suffers from incurable legal defects. The Court should deny the motion to amend and dismiss AbbVie’s claims with prejudice.

BACKGROUND

The Court is by now aware of how the 340B program works. *See id.* at *2–3; Prelim. Inj. Resp., D.23 at 809–11; Mot. Dismiss, D.47 at 1902–04. AbbVie’s attempt to revive this lawsuit springs from a small new wrinkle in the program’s landscape. *See* Compl. Redline, D.53-2 at 2212–14, 2232–33. Recently, federal regulators have announced “a voluntary 340B Rebate Model Pilot Program” applicable to a subset of 340B drugs. *See* HRSA Notice, 90 Fed. Reg. 36,163, 36,164 (Aug. 1, 2025). The manufacturers who make and sell those drugs must “apply” and have their “plans for participation . . . [a]pprov[ed].” *Id.* But those allowed into the program will have an alternative “mechanism” for satisfying their obligation to sell certain drugs at the 340B ceiling price. *Id.* at 36,163. Specifically, federal regulators will let them attempt to provide the 340B discount as a back-end rebate, rather than an up-front sales price reduction. *See id.* at 36,164.

AbbVie alleges it “is preparing an application” to participate in the pilot program. Compl. Redline, D.53-2 at 2214. It does not say what its application will propose, and it cannot know

* Pincites to docket entries use the Page ID file-stamp pagination.

whether federal regulators will approve. *See id.* at 2212–14; *see also* HRSA Notice, 90 Fed. Reg. at 36,164–65 (dictating application “criteria,” *id.* at 36,164). But AbbVie does identify a single blood cancer drug called “Imbruvica” that could in theory be discounted by rebate. Compl. Redline, D.53-2 at 2213. And although AbbVie does not identify a single 340B Hospital in Tennessee to which it is selling Imbruvica, it asserts that “[c]ollecting claims data” from hospitals “is the most accurate and efficient method” of providing Imbruvica rebates. *Id.* at 2214; *see id.* at 2212–14.

Based on these allegations, AbbVie proposes a brand-new preemption claim. *See id.* at 2232–33. The claim is limited to challenging the Hospital Protection Act’s prohibition on manufacturers “requir[ing]” insurance and utilization “data as a condition” for “acqui[ring]” 340B drugs. Hosp. Prot. Act § 1(a)(1), D.23-1 at 837; *see* Compl. Redline, D.53-2 at 2233. And in support of this claim, AbbVie posits (1) that the Hospital Protection Act “prevents manufacturers from requiring basic claims and utilization data from” 340B Hospitals and (2) that this presents a preemptable “obstacle” to Congress’s objectives. Compl. Redline, D.53-2 at 2233.

AbbVie is wrong on both counts; its motion should be denied and this lawsuit dismissed.

ARGUMENT

“The grant or denial of an opportunity to amend is within the district court’s discretion.” *Greer v. Strange Honey Farm, LLC*, 114 F.4th 605, 617 (6th Cir. 2024) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). But it is necessarily an abuse of discretion to grant leave for a futile amendment. *See Stanley v. W. Mich. Univ.*, 105 F.4th 856, 867 (6th Cir. 2024) (citing *U.S. ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 407 (6th Cir. 2016)). “An amendment is futile ‘when, after including the proposed changes, the complaint still could not withstand a . . . motion to dismiss.’” *Id.* (quoting *Skatmore, Inc. v. Whitmer*, 40 F.4th 727, 737–38 (6th Cir. 2022)); *see Greer*, 114 F.4th at 617. That describes the circumstances here.

To survive a motion to dismiss, AbbVie would have to “plead ‘factual content . . . allow[ing] . . . [a] reasonable inference that’” General Skrmetti plans some imminent “‘misconduct.’” *Martinez v. Wayne Cnty.*, 142 F.4th 828, 836 (6th Cir. 2025) (quoting *Crawford v. Tilley*, 15 F.4th 752, 762 (6th Cir. 2021)); see *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bates v. Green Farms Condo. Ass’n*, 958 F.3d 470, 481 (6th Cir. 2020). More specifically, AbbVie would have to allege the concrete circumstances of a “certainly impending” and unlawful prosecution. *Christian Healthcare Ctrs., Inc. v. Nessel*, 117 F.4th 826, 843 (6th Cir. 2024) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)); see *Lindke v. Freed*, 601 U.S. 187, 191 (2024); *Whole Woman’s Health v. Jackson*, 595 U.S. 30, 44 (2021); *L.W. ex rel. Williams v. Skrmetti*, 83 F.4th 460, 490 (6th Cir. 2023); *Ammex, Inc. v. Cox*, 351 F.3d 697, 706–07 (6th Cir. 2003); see also *Mot. Dismiss*, D.47 at 1906–07 (laying out the compound requirements imposed by the Civil Rights Act, the *Ex parte Young* doctrine, and federal standing and ripeness jurisprudence).

AbbVie’s complaint does no such thing, see *Mot. Dismiss*, D.54 at 1906–21; *Mot. Dismiss Reply*, D.54 at 2253–57, and its proposed amendment fails to move the needle. *First*, it gives this Court no basis to conclude that AbbVie will violate the Hospital Protection Act by participating in the pilot program. *Second*, any such violation would not be preempted regardless.

I. AbbVie alleges no viable cause of action arising from the federal pilot program.

AbbVie’s first problem arises from its scant and premature allegations. A plaintiff cannot bring a pre-enforcement challenge to the validity of a state law based on subjective fears about contingent future events. *McLemore v. Gumucio (McLemore I)*, No. 22-5458, 2023 WL 4080102, at *2 (6th Cir. June 20, 2023); see *Younger v. Harris*, 401 U.S. 37, 42 (1971). Rather, the plaintiff must say *how* he intends to violate specific “provisions” of the challenged law, *Doe v. Lee (Lee I)*, 102 F.4th 330, 341 (6th Cir. 2024), and then explain *why* he has reasonable cause to fear “a ‘certainly impending’ threat of prosecution” for doing so. *Friends of George’s, Inc. v. Mulroy*, 108

F.4th 431, 435 (6th Cir. 2024) (emphasis omitted) (quoting *Crawford v. U.S. Dep’t of Treasury*, 868 F.3d 438, 454 (6th Cir. 2017)). AbbVie’s proposed amendments fail to clear these hurdles.

To begin, AbbVie’s interest in moving “promptly” has (once again) prohibited it from allowing its cause of action to ripen. Mot. Amend, D.53 at 2090; *cf.* Prelim. Inj. Resp., D.23 at 812–16 (identifying similar problems with the initial complaint and motion for preliminary relief). Barely a month has passed since federal regulators announced the pilot program. *See* HRSA Notice, 90 Fed. Reg. at 36,163. AbbVie has not provided its application to this Court or even definitively alleged it will submit one. Assuming AbbVie completes the application it “is preparing,” Compl. Redline, D.53-2 at 2214, the application need not be filed until September 15, *see* HRSA Notice, 90 Fed. Reg. at 36,164. And more importantly, the federal government will have an additional month (and may well take longer) to issue “[a]pprovals” for participation. *Id.*

Such scant “factual content” cannot support a “reasonable inference that” AbbVie plans to violate the Hospital Protection Act’s claims-data provision. *Martinez*, 142 F.4th at 836 (quoting *Crawford*, 15 F.4th at 762). Throughout this case, AbbVie has refused to identify the Tennessee hospitals with which it does business. *See* Mot. Dismiss Reply, D.54 at 2253. Now AbbVie wants to litigate a new claim concerning a single drug without alleging any facts about that drug’s utilization, sale, or distribution. *See* Compl. Redline, D.53-2 at 2212–14. AbbVie never attempts to explain why the rebate program it “expect[s]” to operate must encompass (the undisclosed volume of) Imbruvica sales to 340B Hospitals in this State. *See id.* Nor does AbbVie explain how its plans would require it to pry Imbruvica-related claims data “[in]voluntarily” from [Tennessee’s] 340B Hospitals.” Mot. Dismiss Reply, D.54 at 2254 (quoting Mot. Dismiss Resp., D.52 at 2075).

This is especially significant because it is far from clear that federal regulators would even approve AbbVie’s rebate program. According to the guidance, each proposal “should include

assurances that all costs for data submission . . . be borne by the manufacturer.” HRSA Notice, 90 Fed. Reg. at 36,164. And for emphasis, federal regulators have stipulated that “no additional administrative costs of running [a] rebate model shall be passed onto the [340B Hospitals].” *Id.* The Court is thus left to wonder whether — come January — AbbVie will realize its dream of a rebate program for Imbruvica. And more importantly, the Court is left to wonder how that minimally described program would violate the claims-data provision of the Hospital Protection Act.

To be clear, it is far from obvious that rebate programs uniformly violate the Act’s claims-data provision. As General Skrmetti has consistently explained, that provision restricts what manufacturers can “*require[]* . . . as a condition for . . . *delivery* of a 340B drug.” Hosp. Prot. Act, D.23-1 at 837 (emphasis added). And as relevant here, the law defines “340B drug” as any “drug . . . *eligible*” for the 340B discount that is “*purchased* by a 340B [Hospital].” *Id.* at 838 (emphasis added); *see also id.* (cross-referencing Tenn. Code Ann. § 56-7-3119(b), which concerns third-party payor practices not implicated here). But a typical rebate program does not entail “condition[s]” on the initial purchase or delivery of a product. *Id.* at 837; *see, e.g.*, HRSA Notice, 90 Fed. Reg. at 36,163. Instead, it provides a discount on that product through an optional after-purchase “reimbursement.” HRSA Notice, 90 Fed. Reg. at 36,163. It thus stands to reason that a drug “eligible” for the 340B discount could be “purchased” at full price and delivered without data-submission conditions. Hosp. Prot. Act, D.23-1 at 838. And “the amount [ultimately] required to be paid” for that drug “taking into account any rebate” would be a concern of federal law, not the Hospital Protection Act. 42 U.S.C. § 256b(a)(1).

It likewise follows that a manufacturer likely could “requir[e] the submission of . . . claims . . . data . . . as a condition for” *providing a rebate* on a 340B drug, or at least that Tennessee law does not prohibit this in categorical terms. Hosp. Prot. Act, D.23-1 at 837. Rather, it is the federal

government that has historically prevented manufacturers from “implementing . . . rebate model[s] without [federal regulators’] approval.” HRSA Notice, 90 Fed. Reg. at 36,164. And in the hypothetical world where AbbVie gets that “approval,” *id.*, the Hospital Protection Act may not pose any hindrance to AbbVie’s “expect[ed]” conduct, Compl. Redline, D.53-2 at 2214.

II. The federal pilot program does not change this Court’s sound preemption analysis.

Assuming for the sake of argument that AbbVie had alleged facts to support a pre-enforcement suit, AbbVie’s latest preemption theory would still fail as a matter of law. Whether preemption is explicit or implied, its “ultimate touchstone” is congressional will. *Fenner v. Gen. Motors, LLC*, 113 F.4th 585, 594 (6th Cir. 2024) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)); see *Gustafson v. City of Lake Angelus*, 76 F.3d 778, 782–83 (6th Cir. 1996). The Court should not change its assessment of Congress’s intent based purely on the current federal Administration’s announcement of its new pilot program.

It first bears mentioning that the “‘strong presumption’ against implied preemption” still applies to the Court’s assessment of the pilot program. *AbbVie*, 2025 WL 1805271, at *12 (quoting *Torres v. Precision Indus., Inc.*, 995 F.3d 485, 491 (6th Cir. 2021)). The program only offers manufacturers the option of “implementing a [drug-specific] rebate model” to meet their obligation to sell those drugs at the 340B discount. HRSA Notice, 90 Fed. Reg. at 36,164 (citing 42 U.S.C. § 256b(a)(1)). This does not change the fact that the legislation being implemented operates in multiple fields traditionally regulated by the States. See *Minn. ex rel. Whipple v. Martinson*, 256 U.S. 41, 43–45 (1921); *N. Va. Hemp & Agric., LLC v. Virginia*, 125 F.4th 472, 492 (4th Cir. 2025); see also *Pharm. Soc’y of N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (distinguishing between state power and federal power in drug-sales regulation). Indeed, state law makes it possible for prescription drugs, pharmacies, and hospitals to exist. See Tenn. Code Ann. §§ 63-6-236,

63-10-202, 68-11-202(a)(1). And the 340B statute does no more than regulate “the amount required to be paid” for certain drugs in certain sales transactions. 42 U.S.C. § 256b(a)(1).

It would thus strain credulity to conclude that AbbVie’s case for preemption has grown stronger based on the federal executive branch’s announcement of a pilot program through informal guidance. Such guidance does not “have the force and effect of law.” *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–03 & n.31 (1979)). It just “explains how the agency will enforce [the 340B] statute.” *Nat’l Min. Ass’n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014). And the statute has always allowed for “rebate[s]” to be “tak[en] into account” when calculating 340B pricing. 42 U.S.C. § 256b(a)(1). But that does not mean manufacturers *must* offer rebates, much less that they can pursue whatever rebate model they deem “most accurate and efficient.” Compl. Redline, D.53-2 at 2214. Guidance or no guidance, Congress said what it said. And nothing it said manifests an “unmistakably clear” intent to preempt state laws governing manufacturer demands for claims and utilization data from hospitals. *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Will v. Mich. Dep’t of State Police*, 491 U.S. 58, 65 (1989)).

Nor has Congress made clear that such preemption should follow any executive-branch action. To be sure, the supreme “Laws of the United States” can include “federal regulations,” at least so long as they “are properly adopted in accordance with [congressional] authorization.” *State Farm Bank v. Reardon*, 539 F.3d 336, 341 (6th Cir. 2008) (quoting *City of New York v. FCC*, 486 U.S. 57, 63 (1988)). But AbbVie stakes its claim on sub-regulatory guidance, not the sort of binding “federal regulations” that follow notice-and-comment rulemaking. *Id.* (quoting *New York*, 486 U.S. at 63); see *Appalachian Power*, 208 F.3d at 1020; HRSA Notice, 90 Fed. Reg. at 36,163. In fact, Congress has not even “grant[ed the executive branch] general rulemaking authority” for

implementing the 340B statute. *Eli Lilly & Co. v. Kennedy*, No. 21-cv-2608, 2025 WL 1423630, at *9 (D.D.C. May 15, 2025). This leaves AbbVie to stack inference upon innuendo while attempting to color its latest preemption argument.

Even putting these critical issues aside, AbbVie’s effort fails. The guidance document announcing the pilot program does not include “any language” that explicitly or “by implication preempts enforcement” of state law. *Gustafson*, 76 F.3d at 784. It merely offers manufacturers a “voluntary [alternative] mechanism” for complying with federal law. HRSA Notice, 90 Fed. Reg. at 36,163; *see id.* at 36,164. Its failure to mention state law implies, if anything, that all program participants must still “adhere[] to all other . . . [s]tate [law] requirements.” HRSA Notice, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010); *cf. Gustafson*, 76 F.3d at 785 (adopting a similar line of reasoning with respect to actual binding regulations). And since those requirements include a growing list of state laws like the Hospital Protection Act, *see* Compl. Redline, D.53-1 at 2218–19, one would expect federal regulators to address preemption explicitly rather than “hid[ing]” that “elephant[] in [a] mousehole[.]” *Whitman v. Am. Trucking Ass’n*s, 531 U.S. 457, 468 (2001); *see Bond v. United States*, 572 U.S. 844, 862 (2014).

Nor has AbbVie identified so much as a mousehole for preemption to hide in. AbbVie simply claims that the guidance “confirms” federal law grants manufacturers a “right . . . to request claims data from” 340B Hospitals and that federal regulators have assumed 340B Hospitals “will submit [such] data” to manufacturers. Compl. Redline, D.53-2 at 2214. But far from assuming manufacturers can *require* such claims-data submissions from 340B Hospitals, the guidance says these rebate programs should saddle those same Hospitals with “no additional administrative costs.” HRSA Notice, 90 Fed. Reg. at 36,164. This is consistent with federal regulators’ explicitly stated view of the pilot program. That is, it provides an opportunity to test rebate models that

“would [otherwise] violate” *federal* law. *Id.* But if a manufacturer cannot run a rebate program in a particular state without violating *state* law, the guidance implies — if anything — that the manufacturer should not “volunt[eer]” to run such a program. *Id.*

* * *

All of this leaves AbbVie in the same place it already was. AbbVie has every right to submit an application for the federal pilot program. And assuming its application is approved, it may be able to sell Imbruvica in Tennessee by guaranteeing the 340B price through a rebate. But none of this helps AbbVie correct its failure to file a well-pleaded complaint. This Court should recognize as much, reject the motion to amend, and grant General Skrmetti’s motion to dismiss.

CONCLUSION

This Court should deny AbbVie’s motion to amend and dismiss AbbVie’s lawsuit.

Dated: September 10, 2025

Respectfully submitted,

JONATHAN SKRMETTI
Tennessee Attorney General & Reporter

JESSICA S. BERK
Acting Assistant Attorney General

/s/ Gabriel Krimm
GABRIEL KRIMM
Senior Assistant Solicitor General
Office of the Tennessee
Attorney General & Reporter
P.O. Box 20207
Nashville, TN 37202-0207
(615) 532-5596
BPR No. 036087
Gabriel.Krimm@ag.tn.gov
Counsel for the Attorney General

CERTIFICATE OF SERVICE

I certify that I filed the above document using the Court's CM/ECF system on September 10, 2025, which electronically served a copy to all counsel of record:

Jorie Edith Zajicek
Matthew S. Owen
Meredith M. Pohl
Minton P. Mayer
Counsel for Plaintiffs

Jessica S. Berk
Gabriel Krimm
Counsel for the Attorney General

/s/ Gabriel Krimm
Gabriel Krimm